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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,837	07/20/2001	Joseph A. Monforte	14-020510US	8812

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,837	MONFORTE, JOSEPH A.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10-13,15-35 and 37-39* is/are pending in the application.

4a) Of the above claim(s) *6,24-29 and 37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7,8,10-13,15-23 and 30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Claims 6, 24-29 and 37-39 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 10/16/03.

An action on the merits of elected claims 1-2, 4-5, 7-8, 10-13, 15-23 and 30-35, as they read on the elected species, follows. All objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 112, 1st para

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-5, 7-8, 10-13, 15-23 and 30-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A first set of compositions capable of causing a first demonstrated therapeutic activity, and capable of causing a second desired activity related to a different disease

areas of interest, as recited in claims 1 and 18, are new matter. In addition, a modified cell line which differs from a parent cell line "in at least one selected protein or nucleic acid", as recited in claim 1, is new matter.

With regard to first and second activities, original claim 1 recited a set of compositions comprising only a "first demonstrated activity" and a "second desired activity", but did not limit these to any particular activities. Original claim 9 limited a "set of compounds" of claim 1 to be drug compositions identified as *treatment for* the first demonstrated activity. This is in contrast to the instantly limitation for compositions capable of *causing* a therapeutic activity. *Treating* an activity, which is generally interpreted to be amelioration, inhibition, antagonism, etc. is quite different from *causing* an activity to occur. Original claims 10-11 limited the second activity to be antiproliferative or antineoplastic. While it is acknowledged that antiproliferative and antineoplastic activities may be correlated with either or both of occurrence of disease and treatment of disease, the original claims did not actually limit the second desired activity to be "related" to any disease or disorder.

The original specification repeats the language of the original claims on at least pages 1-2, 6-8 and 15. The original specification discloses on page 2, lines 25-29 that a modified cell line may differ from its parent in the activity or concentration of a selected protein or nucleic acid *in response to* the addition of one or more agents. Page 2, lines 30-35 further discloses that a set of compounds maybe those identified for *treating* a first demonstrated activity. The specification does not disclose anywhere that a composition is capable of *causing* a therapeutic activity. Page 6 discloses in lines 14-

18 that it is possible to correlate a set of responses (of a cell line) with a desired activity, thereby allowing screening for compositions which produce a desired *response profile*. Page 6 further discloses that the compositions which have one or more desired activities are those which evoke a preferred pattern of genetic and cellular responses in cells. The response profile is not disclosed as either a therapeutic activity nor specifically related to a "different" disease of interest. The specification sets forth presumptive examples of screening on pages 25-26, but nowhere discloses compositions capable of causing a therapeutic activity nor a "second desired activity" specifically related to a disease. For these reasons, the new limitations introduce new matter.

With regard to a modified cell line which differs from a parent cell line in at least one selected protein or nucleic acid, it is noted that original claim 2 limited a modified cell line to differ from its parent in the "activity or concentration" of a selected protein or nucleic acid. Page 7 of the originally filed specification provides support for original claim 2. Nowhere do the original claims or specification recite or disclose a modified cell line which differs from its parent by the absence or presence, per se, of a selected protein or nucleic acid, or by the presence of a modified/mutated/homologous protein or nucleic acid. As the new limitation is broader in scope than that originally recited/disclosed, the embodiments encompassed by the broader limitation introduce new matter.

In the response filed 6/15/05, applicant merely states that "support is replete throughout the specification" for the new limitations, but does not point, by page and line number, original claim number, Figure element, etc. to support in the originally filed disclosure for the new limitations of the claims. As the originally filed claims and specification fail to support the new limitations, as set forth above, the claims are rejected for reciting new matter.

Claim Rejections - 35 USC § 112, 2nd para

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-5, 7-8, 10-13, 15-23 and 30-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 18 recite a "different disease area of interest". As no disease is recited elsewhere in the claims, it is unclear what is intended by a "different" disease, therefore the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-5, 12, 15-19, 21, 30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Amin et al. (US 5,759,836).

AMIN teaches a method of screening for (i.e. identifying) compositions which inhibit nitric oxide synthase (NOS; i.e. a desired activity) related to osteoarthritis by providing a set of compositions which are capable of inhibiting COX and/or iNOS (first demonstrated therapeutic activities) and wherein at least one member of the set of compositions is capable of causing the (second) desired activity (col. 6, lines 39-43, col's 20-22 and Table 2). As inhibition of COX and iNOS is related to treatment of diseases related to inflammation (col. 2, lines 51-63), and osteoarthritis is not an inflammatory disease, the second desired activity (OA-NOS inhibition) one which is "different" from the demonstrated therapeutic activity (anti-inflammatory activity). AMIN teaches that his assay is carried out with murine macrophage cells and bovine chondrocytes wherein the cells are modified treated with LPS to induce iNOS and/or COX-2 (col. 20, lines 24-67), thus teaching a plurality of cell lines wherein modified cell lines differ from their parents in the activity and concentration of at least one selected protein. AMIN teaches detecting the activities of the selected proteins in cells exposed

to the test compositions and correlating these responses (i.e. genetic response profile) to the therapeutic and desired activities to identify a pattern corresponding a decrease in one activity and an increase in the other, and to thus identify a composition with the desired activity (Tables 1 and 2), thereby anticipating claims 1-2, 4-5, 12, 15-19 and 34. AMIN further teaches administering varying concentrations of his compositions and presents a comparative analysis of his data (col. 21, line 4-col. 22, line 19), thus anticipating claims 21 and 30.

Double Patenting

Claims (2 and 16), 15, 17, 5, 31, and 32 of this application conflict with claims 1, 2, 4, 16, 28 and (29-32), respectively, of Application No. 09/811,378. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Although the claims differ slightly in scope, the limitations of the instant claims are encompassed by the broader claims of application 09/811,378, and thus conflict.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
8/16/05